ALFRED MANN FOUNDATION

Medical Micropower Network Service in the 413-457 MHz Band

David Hankin
Chief Executive Officer
Alfred E. Mann Foundation for Scientific Research
October, 2009

ALFRED MANN FOUNDATION

Background

- FCC adopted a rulemaking that would provide secondary access to 413-457 MHz spectrum for wideband medical service
  - NPRM issued in March, 2009
  - Initial comment period ended on August 11, 2009
  - Reply period concluded on September 11, 2009

ALFRED MANN FOUNDATION

Alfred Mann Foundation

- Founded in 1985
- Non-profit engaged solely in medical research
- Initiated R&D on numerous advanced medical devices
  - Cochlear implant (hearing impaired)
  - Retinal prosthesis (vision)
  - Fully implantable glucose sensor (diabetes)
  - Microstimulator system (movement disorders)

ALFRED MANN FOUNDATION

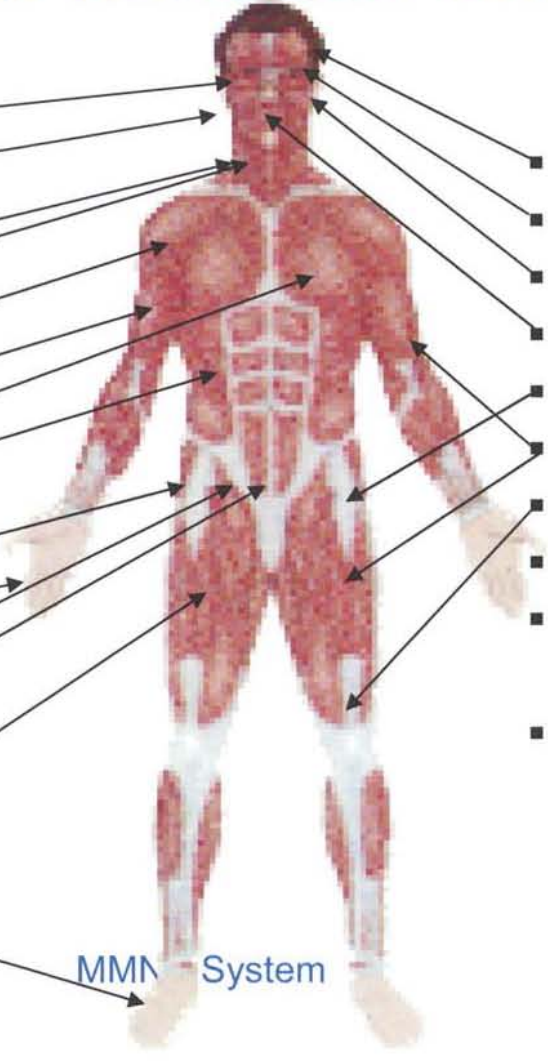
AMF Microstimulator System

- Movement Disorders
  - Restores function and sensation to paralyzed limbs and organs
    - Traumatic brain injury (signature injury from conflicts)
    - Stroke (~800,000 per year in US)
    - Spinal cord injury (~12-15K per year in US)
    - Multiple Sclerosis
    - Cerebral palsy
- Advanced Prosthesis
  - Provides wireless sensation and control to next generation prosthesis
    - Lower weight
    - Direct neural control

ALFRED MANN FOUNDATION

AMF's Disruptive Technology May Revolutionize Medical Treatment

- Eyelid droop
- Facial palsy
- Shoulder Subluxation
- Sleep apnea
- Muscle atrophy
- Arm/hand rehab
- Cardiac assist
- Cough
- Pressure Ulcers
- Spasticity
- Bladder control
- Bowel control
- Gait rehabilitation
- Foot drop

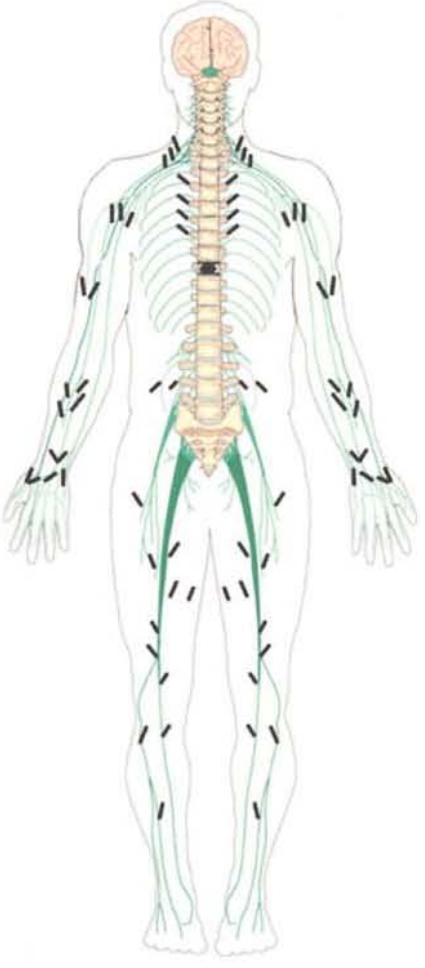


- Parkinson's disease
- Cerebral Palsy
- Vertigo
- Dysphagia
- FES Exercise
- Smart Prosthesis
- Arthritis
- Nerve Repair
- Nerve Regrowth

- And many more to come

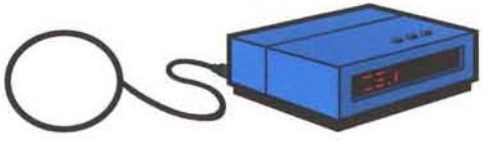
ALFRED MANN FOUNDATION

AMF Microstimulator System



MCU

Clinician's Programmer



Charger

Microstimulator Implant

ALFRED MANN FOUNDATION

No Comparable System Exists

ALFRED MANN FOUNDATION

Project Evolution

- 9 years in development
- 120 person team consisting of approximately 90 scientists of various disciplines
- To date, ~$100 million (in tax exempt dollars) invested in development
  - Estimate $120 million to complete
- Working with FDA, FCC, NTIA and other regulators for several years

ALFRED MANN FOUNDATION

Experimental Progress

- **January, 2005**
  - FCC grants experimental license to AMF in 410-470 frequencies
  - Renewed in 2009
- **2005-2007**
  - UK clinical trial demonstrates system will restore hand and arm movement in paralyzed post-stroke patients
- **2006-2008**
  - AMF commences pre-clinical studies of battery powered prototype microstimulators *in vivo* testing to verify biocompatibility and *in vitro* testing to verify RF operations
- **April, 2008**
  - AMF implants 2 operating MMNS devices into laboratory animal
  - Device stimulating and communicating
- **Q3,Q4 2008**
  - AMF expects to complete construction of first 200 fully functioning, implantable microstimulators
- **2009**
  - Human trial at Walter Reed with experimental device
- **May, 2010**
  - Human clinical trials expected under FDA auspices

ALFRED MANN FOUNDATION

AMF Requests Secondary Access to Four, 5 MHz channels

413 – 419 MHz
426 – 432 MHz
438 – 444 MHz
451 – 457 MHz

ALFRED MANN FOUNDATION

Current Channel Allocation

INTERNATIONAL TABLE	UNITED STATES TABLE		FCC RULE PART(S)
* * * * *	Federal Table (MHz)	Non-Federal Table (MHz)	
* * * * *	**410-420** FIXED US13 MOBILE SPACE RESEARCH (space-to-space) 5.268 G5 US399	**410-420** US13 US399	**Private Land Mobile (90)** **Personal (95)**
* * * * *	**420-450** RADIOLOCATION US217 G2 G129 5.286 US7 US87 US230 US397 G8 US399	**420-450** Amateur US7 NG135 5.282 5.286 US87 US217 US230 US397 US399	**Private Land Mobile (90)** **Amateur (97)** **Personal (95)**
* * * * *	**450-454** 5.286 US87 US399	**450-454** LAND MOBILE 5.286 US87 US399 NG112 NG124	**Auxiliary Broadcasting (74)** **Private Land Mobile (90)** **Personal (95)**
* * * * *	**454-456**	**454-455** FIXED LAND MOBILE US399 NG12 NG112 NG148	**Public Mobile (22)** **Maritime (80)** **Personal (95)**
		455-456 LAND MOBILE US399	**Auxiliary Broadcasting (74)** **Personal (95)**
* * * * *	**456-460** 5.287 5.288 US399	**456-460** FIXED LAND MOBILE 5.287 5.288 US399 NG112 NG124 NG148	**Public Mobile (22)** **Maritime (80)** **Private Land Mobile (90)** **Personal (95)**

ALFRED MANN FOUNDATION

Interference Mitigation

- Microstimulator devices pose virtually no risk of harmful interference to incumbent users in the 413-457 MHz band
- Microstimulator system is designed to avoid harmful interference from other systems

ALFRED MANN FOUNDATION

Comments on MMN NPRM

- Supporters
  - Filed comments strongly supporting FCC proposal to allow MMN devices in the 413-457 MHz band
    - More than 50 supporting parties
    - Include a broad spectrum of interests, including Congressional leaders, government agencies, veterans organizations, medical research and treatment establishments, non-profit organizations, equipment manufacturers, doctors, scientists, and individuals with disabilities
- Detractors
  - Filed comments opposing the proposed MMN operations
    - Only a handful of parties
    - Include incumbent land mobile radio (APCO, LMCC, Motorola), broadcast auxiliary (MSTV and SBE), and amateur radio (ARRL)

ALFRED MANN FOUNDATION

Opposing Comments

- **MMN opponents concede significant public interest benefits offered by MMNs**
- Speculate, without support, that other spectrum alternatives are viable
  - WMTS spectrum in the 608-614 MHz band
  - Part 90 medical telemetry spectrum above 450 MHz are viable spectrum alternatives
- Unfounded claims of harmful interference, primarily from incumbent services to MMNs
- Motorola offered the only technical analysis
  - Purports to show harmful interference from MMNs to land mobile radio
  - Analysis fatally flawed due to reliance upon erroneous or irrelevant assumptions
- No party alleged harmful interference from MMNs to remote pickup broadcast or amateur radio services

ALFRED MANN FOUNDATION

Response to MMN Opponents

- Lower 400 MHz band is ideal for wireless medical implant devices
  - Conclusion supported by data and accepted by both the FCC and the scientific community
  - Critical factors support conclusion
    - RF signal propagation within the human body
    - physical size and power consumption of implant devices
    - international frequency compatibility
- WMTS and Part 90 medical telemetry spectrum are unsuitable
  - over-populated with other commercial, high-power transmitters
  - FCC rules limit the use of these bands to health care facilities to measure and record patient-related information
  - Mobile, more complex functions of MMN devices fall well outside the intended use of these frequencies

ALFRED MANN FOUNDATION

Response to MMN Opponents

- MMNs are designed specifically to avoid causing harmful interference to incumbent services through numerous operational factors and techniques
  - low power operation
  - low duty cycle
  - wideband operation
  - near-ground operation.
- MMNs will not receive harmful interference from incumbent services
  - message coding
  - spectral notching
  - dynamic channel switching
  - wideband operation
  - timing and filtering

ALFRED MANN FOUNDATION

Joint Interference Analysis with JSC

- AMF has entered into an agreement with JSC to perform interference analysis and, if required, testing to determine RF compatibility between MMNs and incumbent government operations, including LMR and radiolocation systems, in the 413-450 MHz band.
- The joint interference analysis is expected to commence in fiscal year 2010.
- AMF expects that the results will satisfy concerns regarding potential interference to and from both government and non-government operations, including LMR, radiolocation, remote pickup broadcast, and amateur radio services.

ALFRED MANN FOUNDATION

AMF Time Imperative

- AMF and scientific collaborators expect to commence clinical trials in 2010 to address stroke, spinal cord injury, traumatic brain injury and arthritis conditions. Expected clinical partners include
  - Walter Reed Army Medical Center
  - Navy
  - Veterans' Administration
  - Shriner's Children's Hospital
  - USC
- AMF anticipates that the microstimulator system will be widely deployed to treat returning soldiers from Iraq and Afghanistan conflicts